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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/763,902	06/13/2001	Y Tom Tang	PF-0577 USN	3561

27904 7590 02/25/2004

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EXAMINER

WAX, ROBERT A

ART UNIT PAPER NUMBER

1653

DATE MAILED: 02/25/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Interview Summary	Application No.	Applicant(s)	
	09/763,902	TANG ET AL.	
	Examiner	Art Unit	
	Robert A. Wax	1653	

All participants (applicant, applicant's representative, PTO personnel):

- (1) Robert A. Wax. (3)____.
- (2) Shirley Recipon. (4)____.

Date of Interview: 20 February 2004.

Type: a) ☒ Telephonic b) ☐ Video Conference
c) ☐ Personal [copy given to: 1) ☐ applicant 2) ☐ applicant's representative]

Exhibit shown or demonstration conducted: d) ☐ Yes e) ☒ No.
If Yes, brief description: _____.

Claim(s) discussed: none.

Identification of prior art discussed: none.

Agreement with respect to the claims f) ☐ was reached. g) ☐ was not reached. h) ☒ N/A.

Substance of Interview including description of the general nature of what was agreed to if an agreement was reached, or any other comments: Ms. Recipon pointed out that there were words missing in a sentence on page 6 of the Office action mailed February 13, 2004. Examiner has corrected the error and attaches a revised copy of the Office action. The time period for response is NOT reset since the error is typographical in nature. No response to nor summary of this interview is necessary.

(A fuller description, if necessary, and a copy of the amendments which the examiner agreed would render the claims allowable, if available, must be attached. Also, where no copy of the amendments that would render the claims allowable is available, a summary thereof must be attached.)

THE FORMAL WRITTEN REPLY TO THE LAST OFFICE ACTION MUST INCLUDE THE SUBSTANCE OF THE INTERVIEW. (See MPEP Section 713.04). If a reply to the last Office action has already been filed, APPLICANT IS GIVEN ONE MONTH FROM THIS INTERVIEW DATE, OR THE MAILING DATE OF THIS INTERVIEW SUMMARY FORM, WHICHEVER IS LATER, TO FILE A STATEMENT OF THE SUBSTANCE OF THE INTERVIEW. See Summary of Record of Interview requirements on reverse side or on attached sheet.

Examiner Note: You must sign this form unless it is an Attachment to a signed Office action.

Examiner's signature, if required

Summary of Record of Interview Requirements

Manual of Patent Examining Procedure (MPEP), Section 713.04, Substance of Interview Must be Made of Record

A complete written statement as to the substance of any face-to-face, video conference, or telephone interview with regard to an application must be made of record in the application whether or not an agreement with the examiner was reached at the interview.

Title 37 Code of Federal Regulations (CFR) § 1.133 Interviews

Paragraph (b)

In every instance where reconsideration is requested in view of an interview with an examiner, a complete written statement of the reasons presented at the interview as warranting favorable action must be filed by the applicant. An interview does not remove the necessity for reply to Office action as specified in §§ 1.111, 1.135. (35 U.S.C. 132)

37 CFR §1.2 Business to be transacted in writing.

All business with the Patent and Trademark Office should be transacted in writing. The personal attendance of applicants or their attorneys or agents at the Patent and Trademark Office is unnecessary. The action of the Patent and Trademark Office will be based exclusively on the written record in the Office. No attention will be paid to any alleged oral promise, stipulation, or understanding in relation to which there is disagreement or doubt.

The action of the Patent and Trademark Office cannot be based exclusively on the written record in the Office if that record is itself incomplete through the failure to record the substance of interviews.

It is the responsibility of the applicant or the attorney or agent to make the substance of an interview of record in the application file, unless the examiner indicates he or she will do so. It is the examiner's responsibility to see that such a record is made and to correct material inaccuracies which bear directly on the question of patentability.

Examiners must complete an Interview Summary Form for each interview held where a matter of substance has been discussed during the interview by checking the appropriate boxes and filling in the blanks. Discussions regarding only procedural matters, directed solely to restriction requirements for which interview recordation is otherwise provided for in Section 812.01 of the Manual of Patent Examining Procedure, or pointing out typographical errors or unreadable script in Office actions or the like, are excluded from the interview recordation procedures below. Where the substance of an interview is completely recorded in an Examiners Amendment, no separate Interview Summary Record is required.

The Interview Summary Form shall be given an appropriate Paper No., placed in the right hand portion of the file, and listed on the "Contents" section of the file wrapper. In a personal interview, a duplicate of the Form is given to the applicant (or attorney or agent) at the conclusion of the interview. In the case of a telephone or video-conference interview, the copy is mailed to the applicant's correspondence address either with or prior to the next official communication. If additional correspondence from the examiner is not likely before an allowance or if other circumstances dictate, the Form should be mailed promptly after the interview rather than with the next official communication.

The Form provides for recordation of the following information:

- Application Number (Series Code and Serial Number)
- Name of applicant
- Name of examiner
- Date of interview
- Type of interview (telephonic, video-conference, or personal)
- Name of participant(s) (applicant, attorney or agent, examiner, other PTO personnel, etc.)
- An indication whether or not an exhibit was shown or a demonstration conducted
- An identification of the specific prior art discussed
- An indication whether an agreement was reached and if so, a description of the general nature of the agreement (may be by attachment of a copy of amendments or claims agreed as being allowable). Note: Agreement as to allowability is tentative and does not restrict further action by the examiner to the contrary.
- The signature of the examiner who conducted the interview (if Form is not an attachment to a signed Office action)

It is desirable that the examiner orally remind the applicant of his or her obligation to record the substance of the interview of each case. It should be noted, however, that the Interview Summary Form will not normally be considered a complete and proper recordation of the interview unless it includes, or is supplemented by the applicant or the examiner to include, all of the applicable items required below concerning the substance of the interview.

A complete and proper recordation of the substance of any interview should include at least the following applicable items:

- 1) A brief description of the nature of any exhibit shown or any demonstration conducted,
- 2) an identification of the claims discussed,
- 3) an identification of the specific prior art discussed,
- 4) an identification of the principal proposed amendments of a substantive nature discussed, unless these are already described on the Interview Summary Form completed by the Examiner,
- 5) a brief identification of the general thrust of the principal arguments presented to the examiner,
(The identification of arguments need not be lengthy or elaborate. A verbatim or highly detailed description of the arguments is not required. The identification of the arguments is sufficient if the general nature or thrust of the principal arguments made to the examiner can be understood in the context of the application file. Of course, the applicant may desire to emphasize and fully describe those arguments which he or she feels were or might be persuasive to the examiner.)
- 6) a general indication of any other pertinent matters discussed, and
- 7) if appropriate, the general results or outcome of the interview unless already described in the Interview Summary Form completed by the examiner.

Examiners are expected to carefully review the applicant's record of the substance of an interview. If the record is not complete and accurate, the examiner will give the applicant an extendable one month time period to correct the record.

Examiner to Check for Accuracy

If the claims are allowable for other reasons of record, the examiner should send a letter setting forth the examiner's version of the statement attributed to him or her. If the record is complete and accurate, the examiner should place the indication, "Interview Record OK" on the paper recording the substance of the interview along with the date and the examiner's initials.

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Group II in Paper No. 04222003 is acknowledged. The traversal is on the ground(s) that DNA and protein share a special technical feature since the examples in the PCT Administrative Rules say so. This is not found persuasive because there is no per se rule as to what shares a special technical feature and what does not. The structure of the DNA is extremely different from the structure of the protein and both have widely divergent activities. For these reasons, the DNA and protein lack a special technical feature. Evidence of this was discussed previously where Kain et al. taught a polynucleotide substantially identical to SEQ ID No. 1. Where the sequence exists in the prior art, unity of invention is lacking. The cancellation of SEQ ID No. 1 from the claims does not eliminate the finding.

The requirement is still deemed proper and therefore continues to be FINAL.

Part of the arguments is, however, convincing and the examiner hereby rejoins composition claims 32 and 34 with claim 21. The question of rejoinder of method claims 36, 37 and 38 will be taken up when the protein claims are examined, should a divisional application be filed.

Information Disclosure Statement

2. The information disclosure statement filed November 10, 2003 has been considered. Please see the attached initialed PTO-1449.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 22 and 26 are again rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 22 and 26 recite the limitation "claim 21". However, claim 21 remains withdrawn as directed to a non-elected invention and therefore there is insufficient antecedent basis for this limitation in the claims as to the language (claim 21).

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 22-24 and 26 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claim 22 claims DNA encoding biologically active fragments of the listed SEQ ID Nos. and DNA encoding immunogenic fragments of the listed SEQ ID Nos. This comes, of course from parts (c) and (d) of claim 21. The scope of the instant claims is not commensurate with the enablement of the instant disclosure, because practice of the claimed invention would require undue experimentation by an artisan of ordinary skill in the art. The instant specification is not enabling for biologically active fragments or immunogenic fragments.

The factors to be considered in determining whether undue experimentation is required are summarized in *re Wands* 858 F.2d 731, 8 USPQ2d 1400 (Fed. Cir, 1988). The court in *Wands* states: "Enablement is not precluded by the necessity for some experimentation such as routine screening. However, experimentation needed to practice the invention must not be undue experimentation. The key word is 'undue,' not 'experimentation.'" (*Wands*, 8 USPQ2d 1404). Clearly, enablement of a claimed invention cannot be predicated on the basis of quantity of experimentation required to make or use the invention. "Whether undue experimentation is needed is not a single, simple factual determination, but rather is a conclusion reached by weighing many factual considerations." (*Wands*, 8 USPQ2d 1404). The factors to be considered in

Art Unit: 1653

determining whether undue experimentation is required include: (1) the quantity of experimentation necessary, (2) the amount or direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims. Although the quantity of experimentation alone is not dispositive in a determination of whether the required experimentation is undue, this factor does play a central role. For example, a very limited quantity of experimentation may be undue in a fledgling art that is unpredictable where no guidance or working examples are provided in the specification and prior art, whereas the same amount of experimentation may not be undue when viewed in light of some guidance or a working example or the experimentation required is in a predictable established art. Conversely, a large quantity of experimentation would require a correspondingly greater quantum of guidance, predictability and skill in the art to overcome classification as undue experimentation. In *Wands*, the determination that undue experimentation was not required to make the claimed invention was based primarily on the nature of the art, and the probability that the required experimentation would result in successfully obtaining the claimed invention. (*Wands*, 8 USPQ2d 1406).

Thus, a combination of factors which, when viewed together, would provide an artisan of ordinary skill in the art with an expectation of successfully obtaining the claimed invention with additional experimentation would preclude the classification of that experimentation as undue. A combination of *Wands* factors which provide a very

Art Unit: 1653

low likelihood of successfully obtaining the claimed invention with additional experimentation, however, would render the additional experimentation undue.

In the instant case, it would not require undue experimentation to create pieces of DNA encoding fragments of polypeptide and expressing the DNA to make the polypeptide fragments. It would, however, require undue experimentation to test those fragments for any nonspecified biological activity or immunogenicity. Specifically, with regard to the Wands factors, (1) the quantity of experimentation is huge, since the number of possible biological activities is huge and the number of fragments is also very large, (2) the specification provides no guidance as to what biological activity is to be tested for and no guidance as to how to test for any particular biological activity or immunogenicity. It is clear from the prior art that the specification is correct to identify the claimed polypeptides as being involved in transport of proteins. However, there is no disclosure as to which portions of the proteins may be responsible for the activity. This type of guidance is needed for one of skill in the art to practice the invention. Continuing, (3) the specification is devoid of any working examples of biologically active fragments or immunogenic fragments, (4) the nature of the invention is the discovery of a new protein transport protein, (5) the state of the prior art is such that it seems reasonable to characterize the polypeptides as is done in the specification, (6) the relative skill of those in the art is extremely high, (7) it is totally unpredictable whether any fragment will retain any particular biological activity or be immunogenic and, (8) the claims are considered very broad with regard to the fragments with the claimed activity. Thus, the conclusion of undue experimentation is dictated.

7. Claims 22-24 and 26 are also rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. As discussed above in the enablement rejection, the claims read on DNA encoding biologically active fragments and immunogenic fragments of the recited SEQ ID Nos. While applicants are in possession of all fragments since the entire sequences are disclosed, applicants have not demonstrated that they are in possession of fragments with the recited activities. There is no disclosure as to which portions of the polypeptides might be responsible for the transport activity and the specification demonstrates no other biological activity. Similarly, although epitopes may be on the order of six amino acids in size, not all six-amino-acid fragments would be expected to be immunogenic. There is no disclosure of the three-dimensional structure of the polypeptides and therefore no information as to which amino acids might be located on the outside of the protein molecule and, thus, be candidates for immunogenicity. To summarize, there is no structure-to-function relationship disclosed which would be necessary to establish possession of the claimed invention. Cancellation of the fragment language from the claims would overcome both rejections under the first paragraph of 35 USC 112.

Response to Arguments

8. Applicant's arguments filed November 10, 2003 have been fully considered but they are not persuasive. The rejection of claims 22 and 26 as indefinite has been maintained. Applicants argue that the rejection is improper in view of the incorrect restriction requirement. Since the restriction has not been determined to be incorrect the rejection stands. Should applicants petition and have the restriction altered, this rejection would become moot.

With regard to the anticipation rejection, applicants removed reference to SEQ ID Nos. 1 and 9 from the claims, thus rendering the rejection moot.

Allowable Subject Matter

9. Claims 28-31, 35, 36 and 39 are allowed. The prior art does not teach polynucleotides with the claimed sequences, the specification provides utility and enablement and, thus the above claims are deemed allowable.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert A. Wax whose telephone number is (571) 272-0623. The examiner can normally be reached on Monday through Friday, between 9:00 AM and 5:30 PM.

Art Unit: 1653

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher S. F. Low can be reached on (571) 272-0951. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A handwritten signature in black ink, appearing to read 'Robert A. Wax', is positioned above the printed name.

Robert A. Wax
Primary Examiner
Art Unit 1653